
Haemopoietic Progenitor Cell Apheresis using the Cobe Spectra™

1. PURPOSE

This procedure describes the process for collecting Haemopoietic Progenitor Cells by apheresis (HPC-A), using the Spectra Cobe™ Apheresis System.

2. SCOPE

This procedure applies to all trained Apheresis Nurses who are involved with the collection of HPC-A from donors who are referred to the Haemopoietic Stem Cell Transplant (HSCT) Programme of the Children's Cancer Centre (CCC) at The Royal Children's Hospital (RCH), Melbourne. Trained Apheresis Nurse refers to Div 1 Nurses in the Ambulatory Care Centre who have been trained and assessed to be competent in HPC-A collection using the Spectra Cobe™ Apheresis System. Nurses who are undergoing apheresis tuition may perform this procedure under direct supervision of a trained Apheresis Nurse in accordance with QS-P-005, Staff Training and Assessment and AP-P-003.

3. RESPONSIBILITY

It is the responsibility of the **Apheresis Nurse (Ambulatory Care Centre)** to;

- Liaise with the Bone Marrow Transplant Clinical Nurse Coordinator (BMT CNC), processing laboratory(s) and the Head of the HSCT Programme or delegate for the duration of the collection.
- Liaise with staff of Paediatric Intensive Care Unit as appropriate (according to patient requirements).
- Perform the HPC collection and label the final product as described in HSCT Programme Standard Operating Procedures.
- Hand over custody of care of the final HPC-A product to the respective laboratory.
- Ensure the donor is stable during and at the completion of the procedure before leaving the collection facility.

It is the responsibility of the **Scientists of the Cell Therapy Flow Cytometry or the CCC Vaccine Laboratory** to;

- Liaise with the BMT CNC, Apheresis Nurse and the Head of the HSCT Programme or delegate.
- Label and accept custody of care of the final HPC-A product for further processing.

It is the responsibility of the **BMT CNC** to;

- Liaise with **ALL** key stakeholders interfaced with the HPC collection and processing course.
- Ensure that **ALL** donors testing is completed prior to commencement of HPC collection.
- Confirm with the donor and parents / caregiver and nursing staff (whilst inpatient) additional instructions for subsequent collections.
- Liaise with the requesting Primary Consultant as appropriate.
- Liaise with the Head of the HSCT Programme or delegate as required.

It is the responsibility of the **Head of the HSCT Programme or delegate** to;

- Authorise commencement of HPC collection.
- Ensure donor assessment before commencement of the HPC collection.
- Ensure that **ALL** Pathology requests and medication orders are completed.
- Oversee the care of the donor during the entire HPC collection(s) process.
- Oversee the collection and processing procedures of HPC-A products within the HSCT Programme.

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- Assess HPC-A final product CD34 yield and authorise additional collections according to the original prescription.
- Liaise with the requesting Primary Consultant as appropriate.

It is the responsibility of the Quality Manager (QM) or equivalent to ensure implementation, maintenance and compliance with this procedure.

4. DEFINITIONS

ACC – Ambulatory Care Centre at the Royal Children's Hospital

BB- Blood Bank

CCC- Children's Cancer Centre.

CD34 – Surrogate marker for haemopoietic stem cell.

CVC – Central venous catheter.

Donor – A person who is the source of cells or tissue for a cellular therapy product.

HPC – Haemopoietic Progenitor Cell

HPC-A – Haemopoietic Progenitor Cells-Apheresis. Peripheral blood collected by apheresis as a source of haemopoietic progenitor cells. Mobilised unless otherwise stated.

HSCT – Haemopoietic Stem Cell Transplant

PICU – Paediatric Intensive Care Unit at the Royal Children's Hospital

TBV- Total Blood Volume

5. EQUIPMENT AND SUPPLIES

- Cobe Spectra™ Apheresis System
- Cardiac Monitoring Unit *
- Cobe Spectra™ White Blood Cell Set- functionally closed. GambroBCT. Cat No: 70620
- ACD-A™ 500ml. Baxter. Cat No: AHB 7898
- 0.9% NaCl 1000ml. Baxter. Cat No: AHB 1324
- 0.9% NaCl 10ml. (x2) Pfizer. Cat No: 61045033
- Cross matched Packed Red Blood Cells (collect from BB just prior to set-up) ##
- Blood Warmer Unit #
- Blood Warmer Coil #
- Sterile Caps. Braun Cat No: 4495101
- Sterile dressing pack.

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- Chlorhexidine in alcohol 70%. David Craig. Galenicals. Cat No: 72138/1
- Bentadine® Antiseptic. MCD Operations Pty. Ltd. Cat No: 411183/14
- Syringes 10ml (x5). Terumo Cat No:SS+10ES
- Blood Gas Syringe.
- 3way tap (as required for calcium infusion)
- FBE K₂ EDTA tube.
- Alcohol wipes. Kendall Webcoll. Cat No: 6818-2
- Sterile Gloves. Ansell Nutex Dermashield.
- Heparin for Vascath care. Pfizer Cat No:61024014(note as approved by RCH Drug Usage Committee)

*Cardiac Monitoring is implemented as per donor requirements.

Denotes equipment required for Cobe Spectra™ "Blood Prime" procedure.

##Note Check Blood requirements -irradiated, leucodepleted.

Documentation:

- Completed Consent for Collection, Storage and Disposal of Haemopoietic Progenitor Cells. CL-F-004
- Completed Request for Stem Cell Processing. CT-F-089.
- Completed Pathology Requests as applicable.
- Completed Blood Bank Release Order as applicable.
- Completed Order for Medication MR690/A
- Apheresis Procedure Record. AP-F-004.

6. PROCEDURE

NOTES:

- Confirm with BMT CNC that scheduled HPC-A collection is proceeding.
- If donor is <15Kg, and / or the Apheresis Clinician has requested the collection to be performed in PICU, confirm bed allocation and transfer the Cobe Spectra™ Apheresis System to the allocated room.
- Determine endpoint for procedure, ie volume to be processed, usually 2xTBV, unless specified otherwise by the Clinician.
- Complete procedure documentation on Apheresis Procedure Record.

6.1 Machine Set-Up

Refer to:

- Cobe Spectra™ Apheresis System. Essentials Guide. Gambro BCT. Lakewood Colorado. AP-E-001. 2007.
- Cobe Spectra™ Apheresis System. Cell Therapy Guide. Chapter 4 SpectraAutoPBSC® Procedure. Gambro BCT. Lakewood Colorado. AP-E-003. 2007.

for more detailed instructions.

6.1.1 Gather equipment as listed in Section 5, check and record all batch numbers and expiry dates as indicated on the Apheresis Procedure Record.

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6.1.2 Prime the machine with 0.9%NaCl and complete alarm testing. This step must be completed prior to setting up the blood prime equipment.

6.1.3 If the donor is an inpatient, ask the ward to arrange transfer.

6.2 Pre HPC Collection

6.2.1 The Apheresis Nurse will explain the HPC Collection procedure to the donor according to the age and development level and to the parent / caregiver.

6.2.2 Ensure that a Consent for Collection, Storage and Disposal of Haemopoietic Progenitor Cells is completed, if not, notify the Head of the HSCT Programme or delegate- Apheresis Clinician. If appropriate, complete the consent according to RCH Policy, Consent-Informed. RCH0040.

6.2.3 Ensure that donor infectious disease and blood group testing has been completed within the last 30days and 7days respectively (prior to Day 1 HPC-A collection). Results are available on CLARA and verified on the Haemopoietic Progenitor Cell Harvest Booking Form CL-F-003. Check **ALL** pending results, if testing has not been requested, organise specimen(s) and request(s) to be done **URGENTLY** by RCH Pathology- Laboratory Services. Notify the Apheresis Clinician, BMT CNC and the processing laboratory of **ALL** incomplete donor testing.

NOTE Laboratory Services information inclusive of specimen collection requirements is available on the RCH Intranet.

6.2.4 If previously unaware of positive infectious markers, forewarn the Apheresis Clinician, BMT CNC and the processing laboratory(s) **ASAP**.

6.2.5 Review the completed HPC prescription, Request for Stem Cell Processing, CT-F-089.

6.2.6 For procedures requiring a blood prime, confirm with BB (XT5829) that a crossmatched unit of packed red blood cells is available also ensure that a valid specimen for crossmatching is available if required post procedure.

6.2.7 Ensure that the donor has been assessed and any applicable medication orders have been completed (MR690/A) by the Apheresis Clinician.

6.2.8 Ensure that baseline investigations have been completed as applicable-FBE, CD34 and ionised Ca²⁺ are a minimum. If testing has not been requested, organise specimens and request marked **URGENT** according to Laboratory Services requirements.

6.2.9 Document baseline observations (Temperature, Pulse, Respiration, Blood Pressure, and SaO₂) and machine calculations of total blood and plasma volumes according to the donor's height and weight.

6.2.10 Report **ANY** abnormal baseline investigations or observations to the Apheresis Clinician and treat accordingly.

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6.3 Machine "Blood Prime" Procedure

Refer to:

- Cobe Spectra™ Apheresis System. Cell Therapy Guide. Maintaining Hemodynamic Stability in Pediatric Apheresis Patients. Pages 1-2 – 1-5. Gambro BCT. Lakewood Colorado. AP-E-003. 2007.

for more detailed instructions.

6.3.1 A "Blood Prime" procedure is required when;

- Ordered by the Apheresis Clinician
- The system's extracorporeal blood volume exceeds 15% of the patient's total blood volume (TBV).

Cobe Spectra™ White Blood Cell Set -tubing blood volume	285ml
"Blood Prime" required if Patients' TBV	≤ 1,900ml

6.3.2 Complete a Blood Bank Release Order and arrange collection of the patients' crossmatched blood from BB.

6.3.3 Check blood products according to organisational requirements RCH Clinical Guideline. Blood Transfusion – Administration of Fresh Blood Products.

6.3.4 Set up the blood prime equipment using aseptic technique; ensure that all **clamps are closed** before attaching the unit of crossmatched packed red blood cells.

NOTE: For Blood Prime using ARCBS Packed Cells, use Haematocrit value of 0.60. No predilution, of the Packed cells is required. *(as per communication by CaridianBCT Clinical Manager)*

6.3.5 Connect the red blood cell filter to the blood and to the machine access line

6.3.6 Attach a blood warmer set to the end of the return line.

6.3.7 Press **CONTINUE** on the Cobe, and use the "blood prime set-up" to divert the saline instead of connecting the access line to the donor.

6.3.8 The AC ratio maybe increased at this stage, so the blood prime is completed within a shorter time period, **BUT READJUST AC RATIO** once the patient is connected for the commencement of the collection.

6.3.9 Continue priming with the "blood prime set-up" until the return line appears to have achieved a hematocrit similar to that of the whole blood. Press **PAUSE**

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6.3.10 Remove "blood prime set-up" from the access line. The machine access and return lines are now available to be connected to the donor. If there is a delay in commencing the procedure, seal lines with sterile caps.

REMEMBER TO READJUST AC RATIO

6.4 Connecting the Donor

6.4.1 Administer any ordered premedication and connect donor to cardiac monitoring if indicated.

6.4.1 Connect the donor either via the Vascath (femoral vein) or peripheral vein (antecubital fossa vein).

6.4.2 Prepare the donor for connection; check that the dressing trolley has all required equipment. Using aseptic technique clean both Vascath ends with chlorhexidine solution, obtain blood return to confirm patency of the Vascath and take blood for **ANY** outstanding blood testing. Flush both lumens with 2mls each of 0.9% NaCl.

6.4.3 Connect the machine access and return lines to the donor.

6.5 Collecting the HPC

Refer to:

- Cobe Spectra™ Apheresis System. Cell Therapy Guide. Chapter 4 SpectraAutoPBSC® Procedure. Gambro BCT. Lakewood Colorado. AP-E-003. 2007.

for more detailed instructions.

6.5.1 Once the procedure is underway, inform either / or Scientists of the Cell Therapy Flow Cytometry (XT5832) or the CCC Vaccine Laboratory (XT5652).

6.5.2 Ionised Ca²⁺ must be checked mid way of procedure.

6.5.3 Complete the Apheresis Procedure Record as required.

6.5.4 Monitor vital signs (Temperature, Pulse, Respiration, Blood Pressure, SaO₂) as indicated by donor, but every 30minutes as a minimum. Regularly assess donor for signs of citrate toxicity and hypotension and other adverse reactions, eg;

- Fever
- Chills
- Hypotension/Hypertension
- Pain (access/return sites, chest or back)
- Acute respiratory distress/stridor/wheeze
- Allergic reaction (anaphylaxis)
- Fluid overload.

6.5.5 Encourage food and fluids as per the donor's request throughout the procedure.

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6.6 Rinse Back

6.6.1 A limited rinse back of the collection line is required when a "Blood Prime" has been performed. (The residual volume of blood in the machine post procedure was supplied to the machine by the "blood prime set-up" during the initial machine prime).

6.6.2 If a blood prime was not performed, the residual volume of blood in the machine is returned to the patient via a rinse back procedure.

6.6.3 Following a rinse back (as required), record the collection values on the Apheresis Procedure Record.

6.7 Post Procedure

6.7.1 Collect and despatch post procedure specimens for FBE and ionised Ca²⁺.

6.7.2 Disconnect donor from the machine. If collection was via a Vascath, connect a constant infusion of heparin into both lumens via syringe drivers. Heparin infusion is required at 5IU/ml (dilute heparin in 0.9%NaCl) at a rate of 2ml/hr and written up as an intravenous order (MR690/A) by the Apheresis Clinician or delegate.

6.7.3 If the collection was via peripheral access, apply pressure bandages to access sites. Repeat the donor's vital signs (Temperature, Pulse, Respiration, Blood Pressure, and SaO₂).

6.7.4 The Apheresis Clinician or delegate will review the donor before discharge home or return to the ward.

6.7.5 Clean and decontaminate the Cobe Spectra™ according to manufacturer's recommendations and complete the Maintenance Record, AP-F-003.

7. ENDPOINT

Haemo dynamically stable patient following HPC-A collection.

Documentation summary;

- Completed Consent for Collection, Storage and Disposal of Haemopoietic Progenitor Cells.
- Completed Request for Stem Cell Processing. CT-F-089.
- Completed Pathology Requests as applicable, sent to Laboratory Services.
- Completed Blood Bank Release Order as applicable, sent to collect crossmatched blood as applicable.
- Completed Order for Medication MR690/A.
- Completed Apheresis Procedure Record.
- Completed Cobe Spectra™ General Maintenance Record. AP-F-003.

8. ATTACHMENTS

Apheresis Procedure Record. AP-F-004

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9. REFERENCES

- 9.1 Cobe Spectra™ Apheresis System. Essentials Guide. Gambro BCT. Lakewood Colorado. AP-E-001. 2007.
- 9.2 Cobe Spectra™ Paediatric Considerations and Accessory Products. In service Student Workbook. Gambro BCT. Lakewood Colorado. AP-E-002. 2007.
- 9.3 Cobe Spectra™ Apheresis System. Cell Therapy Guide. Gambro BCT. Lakewood Colorado. AP-E-003. 2007.
- 9.4 Staff Training and Assessment. QS-P-005. Version 001. 2008.
- 9.5 Apheresis Training Procedure. AP-P-003. Version 001. 2008.
- 9.6 Analysis of factors affecting PBPC collection in low-weight children with malignant disorders. J. Delgado, MC Fernandez-jimenez, A. Martinez et al. Cytotherapy, 6:1, 43-49, 2004.